February 1, 2019

Venus Concept USA Inc.
Yoni Iger
VP QA/RA/CA
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K182094
Trade/Device Name: Family of Venus RF Systems - Heal
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: May 16, 2018
Received: August 3, 2018

Dear Yoni Iger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.02.01 09:33:32 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K182094_____

Device Name
Family of Venus RF Systems – Venus Heal

Indications for Use *(Describe)*

The Venus Heal device is intended for the treatment of the following medical conditions; using the Large and Small applicators for delivery of non-thermal RF combined with massage and magnetic field pulses:

- Relief of minor muscle aches and pain, relief of muscle spasm.
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Owner Name	Venus Concept USA Inc.
Address	1880 N Commerce Pkwy, Suite 2 Weston, Florida, 33326, USA
Contact Person	Dr. Yoni Iger VP QA/RA/CA Venus Concept USA Inc. Yoni@venusconcept.com 888 - 9070115
Summary Preparation Date	July 25, 2018

II. Name of device [21 CFR 807.92 (a) (2)]

Trade or Proprietary Name	**Family of Venus RF Systems - Venus Heal**		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Electrosurgical cutting and coagulation device and accessories Class II	PBX	General & Plastic Surgery Panel	§ 878.4400, Electrosurgical, Cutting & Coagulation & Accessories

III. Predicate Devices [21 CFR 807.92(a) (3)]

510(k) #	**Trade Name**	**Product Code**
K143554	Venus Legacy CX	PBX

IV. Device Description [21 CFR 807.92(a) (4)]

The subject device Venus Heal system is a modification of the legally marketed Venus Legacy CX system cleared under K143554. The proposed system is a smaller and lightweight version of the previously cleared Venus Legacy CX system. The Venus Heal system consists of a console (main unit) and two applicators (Large and Small). The console design change is driven to enhance the ergonomic capabilities of the product family.

The additional changes are summarized below:

a) Ergonomics of the user interface: bigger Liquid Crystal Display (LCD) color touch screen.

c) Tissue manipulation includes manual massage only.

d) Increase of Maximal RF output power.

e) Updated software to reflect hardware changes.

The Venus Heal RF energy, pulsed magnetic fields (PMF) and tissue manipulation are utilized to trigger changes in the tissue which result in muscle spasm relief and pain relief, along with local blood circulation improvement.

Temporary reduction in the appearance of cellulite is similarly achieved by combination of these three main mechanisms: RF and Pulse Magnetic Field (PMF) delivery as well as tissue manipulation,

Consistent with the previous clearance, the system is intended to be used in professional healthcare facilities (prescription use) just as the predicate, and its major components are still the main console unit, and individual modules/hand pieces.

V. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

Intended Use / Indications for Use

The Venus Heal device is intended for the treatment of the following medical conditions; using the Large and Small applicators for delivery of non-thermal RF combined with massage and magnetic field pulses:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

VI. Summary of technological characteristics of the device compared to the predicate[21 CFR 807.92(a)(6)]

The technological principles underlying the subject device and its prior legally marketed iteration (K143554) are the same.

Operation of the modified system involves the delivery of RF energy and PMF through electrodes, similar to the previously cleared device. Energy source types are the same. The technological differences in the subject device as compared to the prior iteration is the slight alteration of the tissue manipulation mechanism and increase of optional maximal RF output. The previously cleared device, the Legacy CX, utilizes a tissue manipulation mechanism which emphasize lead mechanism of massage, assisted by suction. In the subject device this was reduced to massaging technique alone.
The new RF output levels along with PMF delivery are commonly used in the Family of Venus RF Systems, as well as in other previously cleared systems for the same indications for use.

The differences above does not raise new questions of safety or efficacy, as the operation of the device and technological parameters are similar to those of the predicate. Also the summary of the bench testing results verify the performance lack of modification.

VII. Performance Testing [21 CFR 807.92(b)(1)]

IEC 60601-1, Medical Electrical Equipment - Part 1-1: General Requirements For Basic Safety And Essential Performance.
IEC 60601-1 Medical Electrical Equipment Part 1-6 General Requirements for basic safety and essential performance.
IEC 60601-2-2 Medical Electrical Equipment – Part 2-2: Particular Requirements For The Basic Safety and Essential Performance Of High Frequency Surgery Equipment and High Frequency Surgical Accessories.
IEC 60601-1-2 Medical Electrical Equipment- Part1-2 General Requirements for basic safety and essential performance-Collateral Standard Electromagnetic Compatibility Requirements and Tests.

A bench test was performed to verify that RF output power elevation has not changed the temperature stability and raising time to endpoint on skin surface.

The bench test intended to demonstrate the ability of the Venus Heal device to reach and maintain a desired range of temperatures on the surface of the treated human skin during treatment time.

Treatment procedure included the temperature ramp up stage, and the maintenance stage in which the temperature was kept at desired temperature range (per user manual). Results of that bench test demonstrate the capability of the device to maintain the skin temperature of 40-45^{o}C for 10-15 minutes, hence the device meets the labeling specifications per the different anatomies.

In addition software verification and validation testing has been performed, and biocompatibility was confirmed using the same product material as in the predicate device.

In all instances, device functioned as intended and the results observed were as expected.

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Venus Heal system is as safe and effective as its predicate device, the Legacy CX, cleared under K143554. The modified system has the same intended use and indications,

similar technological characteristics, and similar principle of operation as its predicate device. The above discussed slight modifications do not alter the intended use of the device and does not affect its safety and effectiveness when used as labeled. Thus, the Venus Heal system is substantially equivalent to its predicate.